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S/N 10/600,088

MAY 25 2006

PATENTIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	KNUDSON ET AL.	Examiner:	M. MENDOZA
Serial No.:	10/600,088	Group Art Unit:	3734
Filed:	JUNE 20, 2003	Docket No.:	14283.2US01
Title:	GASTRO-ESOPHAGEAL REFLUX DISEASE (GERD) TREATMENT METHOD AND APPARATUS		

CERTIFICATE UNDER 37 C.F.R. 1.6(d):I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office on May 25, 2006.By: 

Name: Linda M. Beckman

SUBMISSION OF DECLARATION AND SUPPLEMENTAL REMARKS

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

With the filing of this Request for Continued Examination, the claims are as amended in Applicants' proposed Amendment Under 37 C.F.R. § 1.116 filed on March 9, 2006 and which were subject to an Advisory Action of April 6, 2006 indicating that the Amendment could not be entered since they would require further consideration and/or search.

In addition, Applicants submit herewith the Declaration of Dr. Virender Sharma, an MD gastroenterologist consultant and associate professor of Medicine and Director of the esophageal clinic at the Mayo Clinic facilities in Scottsdale, Arizona.

Dr. Sharma is familiar with gastric banding surgeries and procedures for the treatment of gastroesophageal reflux disease (GERD) and treatments for obesity. As an expert, he has reviewed International Publication No. WO 01/41671 A2 ("Cigaina"). He notes that Cigaina is limited to the treatment for obesity with no suggestion for the use of Cigaina to treat GERD. He also notes that upon inspection of the Cigaina publication, no portion of the band of Cigaina is placed above the cardiac notch or on the esophagus. He


further opines that such a placement would not be suggested by Cigaina since it would defeat the intent of gastric banding.

The amendments to this application, together with the Declaration of Dr. Sharma, clearly established that the claims now before the Examiner are not shown or suggested by Cigaina. Applicants respectfully submit this application is now in condition for allowance. Consideration and Notice of Allowance are solicited.

Respectfully submitted,

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Date: 5/25/06


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PATENTIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	KNUDSON ET AL.	Examiner:	M. MENDOZA
Serial No.:	10/600,088	Group Art Unit:	3731
Filed:	JUNE 20, 2003	Docket No.:	14283.2US01
Title:	GASTRO-ESOPHAGEAL REFLUX DISEASE (GERD) TREATMENT METHOD AND APPARATUS		

CERTIFICATE UNDER 37 CFR 1.6(d):I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office on May 25 2006.By: Linda M. Beckman
Name: Linda M. Beckman**DECLARATION OF VIRENDER SHARMA, MD**


Virender Sharma, MD, declares as follows:

1. I am a gastroenterology consultant, associate professor of Medicine and Director of the esophageal clinic at Mayo Clinic in Scottsdale, Arizona.
2. My specialty is in gastroesophageal diseases and I have interests in endoscopic treatments for GERD and upcoming endoscopic treatments for obesity.
3. I am informed and believe that Mayo Foundation for Medical Education and Research, a Minnesota charitable corporation, located at 200 First Street SW, Rochester, Minnesota 55905-0001, is a licensee and shareholder of the assignee of the above-referenced patent application.
4. As a gastroenterologist, I treat gastric disorders and I refer patients to surgeons for gastric procedures and I stay abreast of various surgery options. I treat patients for complications from gastric surgery procedures. Specifically, I have dealt with complications from gastric banding procedures such as the Lap-Band procedures.
5. I have reviewed International Publication No. WO 01/41671 A2 ("Cigaina"). The device and surgical method described in Cigaina are directed to gastric bands.

These are well-known procedures for treatment of obesity. I am familiar with gastric banding procedures. In all of such procedures, a belt-like device (the band 1 of Cigaina) is placed around the stomach in such a manner as to divide the stomach into an upper region (above the band) and a lower region (below the band). The regions are separated by a small passageway (stoma) the diameter of which is determined by the amount of tightening of the band.

6. In placement of gastric bands such as Cigaina, no portion of the band is placed above the cardiac notch or on the esophagus. Such a placement is not shown in Cigaina. Further such a placement would not be suggested by Cigaina since such a placement would defeat the intent of gastric banding – namely, formation of a small stomach pouch above the band connected by a greatly reduced passageway to the remainder of the stomach.
7. Cigaina is for the treatment of obesity. There is no suggestion to use Cigaina on any part of the esophagus to treat gastro-esophageal reflux disease (GERD).
8. I make this statement based upon my own information and knowledge and that the facts recited in this Declaration are true and correct to the best of my knowledge. The forgoing statements are made of my own knowledge and are true. I hereby acknowledge I am warned that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001) and may jeopardize the validity of the application or any patent issuing thereon.

5/23/06
Date


Virender Sharma, M.D.